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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,719	01/16/2002	Matthew T. Scholz	57338US002	8633
32692	7590	01/20/2006	EXAMINER	
3M INNOVATIVE PROPERTIES COMPANY			CHOI, FRANK I	
PO BOX 33427			ART UNIT	
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1616

DATE MAILED: 01/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/051,719	<b>Applicant(s)</b> SCHOLZ ET AL.	
	<b>Examiner</b> Frank I. Choi	<b>Art Unit</b> 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 2-12, 14-37, 39-43, 54-56 and 58-63 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-12, 14-37, 39-43, 54-56 and 58-63 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Examiner withdraws the finality of the prior Office Action in order to consider the amended claims as indicated in Interview Summary (10/26/2005).

#### ***Election/Restrictions***

Previously withdrawn claims have been amended to include a substantive cationic-film-forming polymer and indicate that the composition is stable. As such, said claims will now be considered. As such, claims 2-12,14-37, 39-43,54-63 are now pending, with no claims withdrawn as directed to a non-elected invention.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 15 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for use of the specified hydroxycarboxylic acid buffers, does not reasonably provide enablement for any and all derivatives thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

#### ***The nature of the invention:***

The claim is directed to use of derivatives of the specified hydroxycarboxylic acid buffers.

#### ***The state of the prior art and the predictability or lack thereof in the art:***

Since it is uncertain what is and is not included within the scope of the limitation "derivative" it does not appear that the prior art of record enables one of ordinary skill in the art

to use any derivative with the expectation that it would be suitable as a buffer in the claimed invention. As such, it appears that predictability in the prior art of record appears to be low as to “derivatives”.

*The amount of direction or guidance present and the presence or absence of working examples:*

Although the Specification does list a number of buffers and provides working examples of a few of said buffers, the same do not establish that any “derivative” would be effective as a buffer in the claimed invention.

*The breadth of the claims and the quantity of experimentation needed:*

The claim is broad in that it claims any derivative of the specified hydroxycarboxylic acid buffers. As such, it appears that one of ordinary skill in the art would be required to do undue experimentation in order to determine whether a given derivative would be effective as a buffer.

Claims 2-12,14-37,39-43,54-56,58-63 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specified examples which have been shown to be stable, does not reasonably provide enablement for all formulations falling within the scope of the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

*The nature of the invention:*

The invention is directed to antiseptic compositions containing iodine and/or iodophor, hydroxycarboxylic acid buffer in excess of 5 wt-%, water, a substantive film-forming polymer, where in the composition is stable.

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*The state of the prior art and the predictability or lack thereof in the art:*

The prior art does disclose the formulation of stable compositions, however, one of ordinary skill in the art would not be able to predict or would have a low probability of predicting from the prior art which other compositions containing the claimed components would or would not be stable. For example, consider Applicant's declaration (1/10/2005) which tested a modified prior art composition.

*The amount of direction or guidance present and the presence or absence of working examples:*

The specification discloses various components and several working examples which are stable, however, as indicated above with respect to the prior art, one of ordinary skill in the art would not be able to predict or would have a low probability of predicting from said examples what other compositions containing the claimed components would or would not be stable.

*The breadth of the claims and the quantity of experimentation needed:*

The claims are broad in that they claim any antimicrobial agent containing iodine and/or iodophor, any hydroxycarboxylic acid buffer including derivatives thereof, and any substantive cationic film-forming polymers. Although the claims are limited to stable compositions, one of ordinary skill in the art would still have to do undue experimentation to determine what combinations of specified components as well as unspecified components can be combined which would result in a stable composition.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-12, 14-37,39-43,54-56,58-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kross et al. (US Pat. 5,618,841) in view of Beach (US Pat. 3,380,923), Talwalker et al. (US Pat. 5,462,714) , Richter et al. (US Pat. 6,379,685) and Samour et al. (US Pat. 5,807,957).

Kross teaches the antimicrobial compositions containing iodophores, lactic acid, surfactants and the formation of films incorporating the above to form protective barriers having viscosities generally in the range from about 200 to 3,000 centipoise, using a suitable polymeric material which are known to those skilled in the art (See entire document, especially Columns 3-5, Column 6, lines 1-6, Examples I, II, II, IV, V).

Beach teaches that amphoteric surfactants, containing amine and sulfate groups, are suitable for use in preparing iodophore germicides suitable for use in the dairy industry (Columns 1, 2).

Talwalker et al. discloses that addition of buffering agents may result in loss of homogeneity due to iodophor precipitation and that providing sufficient amount of carrier, such as a non-ionic surfactant, will stabilize the iodophor (Column 5, lines 21-39). It is disclosed that the combination of acids, such as lactic acid, with iodine results in synergistic microbiocidal activity (Column 2, lines 15-27, Column 4, lines 3-13).

Richter et al. discloses that in personal care products, alpha-hydroxycarboxylic acids used at levels under 10% have shown to improve skin condition and that it is believed that application of these acidulants on the bovine teat skin would accelerate healing and that the preferred acid is lactic acid (Column 10, lines 26-48). It is disclosed that the pH is buffered to typically from 2.5 to 5.5 with the lower value being a limit to prevent excessive irritation on the teat surface and the upper limit to maintain the antimicrobial effect of the protonated carboxylic acids (Column 12, lines 55-68). It is disclosed that any acidulant and corresponding conjugate weak base could be used (Column 13, lines 1-3). It is disclosed that complexed iodines, unlike other antimicrobial agents, offer the advantage of being easily visible when applied to the teat (Column 16, lines 63-65). It is disclosed that the blend of acidulant and /or antimicrobial can be from 1-12 wt% and the buffer can be from 0-15 wt% (Column 17, lines 50-68, Column 18, lines 1-10).

Samour et al. disclose that cationic film forming polymers have improved durability on skin and if containing quaternary ammonium groups will have antimicrobial properties (Column 8, lines 33-45). It is disclosed that the film-forming polymer can be dispersed in water and include a pharmacologically active agent, such as alpha-hydroxy acids (Column 14, lines 10-56).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the combination of iodophor, lactic acid, and film-forming polymer, amphoteric surfactant and water. However, the prior art amply suggests the same as it is known in the art to prepare film-forming compositions containing iodophore, lactic acid, film-forming polymers, including acrylate polymers, and surfactants, including amphoteric surfactants. Further, one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the combination would form an antimicrobial film suitable for

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use in the dairy field as a teat dip. Further, one of ordinary skill in the art would have been motivated to include a cationic film-forming polymer with the expectation that it would result in a film having greater durability and, if containing quaternary ammonium substituents would increase the antimicrobial activity of the composition. Finally, one of ordinary skill in the art would expect that increasing the amount of surfactant would reduce the risk of instability of the iodophor caused by the addition of significant amounts of buffer.

Examiner has duly considered Applicant's arguments but deems them unpersuasive for the reasons of record and the further reasons below.

Since Brink et al. is no longer part of the rejection herein, Applicant's declaration relative to the instability of a modified Brink et al. composition does not overcome the rejection herein. Further, Brink et al. is not necessary as Samour et al. discloses that cationic polymers have improved durability on skin, i.e. are substantive.

With respect to Applicant's arguments as to the teachings of each reference alone as to the amount of hydroxycarboxylic acid buffer, a range can be disclosed in multiple prior art references instead of in a single prior art. See *Iron Grip Barbell Co., Inc. v. USA Sports, Inc.*, 73 USPQ2d 1225, 1228 (Fed. Cir. 2004).

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.



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Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2-12,14-37,39-43,54-56,58-63 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7,16-25,27,29-44,47-60 of copending Application No. 10/922,262 or claims 1-7, 16-25, 27, 29-44, 47-59 of US Pat. 6,838,078 in view of Kross et al. (US Pat. 5,618,841), Beach (US Pat. 3,380,923), Talwalker et al. (US Pat. 5,462,714), Richter et al. (US Pat. 6,379,685) and Samour et al. (US Pat. 5,807,957).

The cited claims of the above-mentioned application teach a film forming composition comprising polymer containing a hydrophobic polymer, such as methacrylic, water, a surfactant, such as an amphoteric surfactant, which can contain an antimicrobial agent, such as iodophor, and a hydroxy-carboxylic acid buffer, such as lactic acid.

Kross et al. (US Pat. 5,618,841), Beach (US Pat. 3,380,923), Talwalker et al. (US Pat. 5,462,714), Richter et al. (US Pat. 6,379,685) and Samour et al. (US Pat. 5,807,957) are cited herein for the same reasons as above and are incorporated herein to avoid repetition.

The difference between the claims of the cited application and the claimed invention is that the prior art does not expressly disclose the combination of iodophor, lactic acid, an acrylate film-forming polymer, amphoteric surfactant and water. However, the prior art amply suggests the same as it is known in the art to prepare film-forming compositions containing iodophore,

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lactic acid, film-forming polymers, including acrylate polymers, and surfactants, including amphoteric surfactants. Further, one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the combination would form an antimicrobial film suitable for use in the dairy field as a teat dip. Further, one of ordinary skill in the art would have been motivated to include a cationic film-forming polymer with the expectation that it would result in a film having greater durability and, if containing quaternary ammonium substituents would increase the antimicrobial activity of the composition. Finally, one of ordinary skill in the art would expect that increasing the amount of surfactant would reduce the risk of instability of the iodophor caused by the addition of significant amounts of buffer.

Therefore, the claimed invention, as a whole, would have been an obvious modification of the claims of said copending US application or US Patent to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references and the claims of said application.

Examiner notes that only the rejection over the copending US application is a provisional obviousness-type double patenting rejection with respect to the copending US application. The rejection over the US Patent is NOT provisional.

### ***Conclusion***

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.


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If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Gary Kunz, can be reached at 571-272-0887. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

FIC

January 19, 2006



JOHN PAK  
PRIMARY EXAMINER  
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